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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,322	04/07/2004	George Acosta	SENS0011CIP	8527
22862	7590	09/26/2006	EXAMINER	
GLENN PATENT GROUP 3475 EDISON WAY, SUITE L MENLO PARK, CA 94025			WINAKUR, ERIC FRANK	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,322	Applicant(s) ACOSTA ET AL.	
	Examiner Eric F. Winakur	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 28-36, 39-41, 44, 45, 49, 52-59, 66-68, 71-74, 76, 78, 79 and 86-99 is/are rejected.
- 7) ☒ Claim(s) 27, 37, 38, 42, 43, 46-48, 50, 51, 60-65, 69, 70, 75, 77 and 80-85 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/877,529 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

It is noted that application No. 09/877,529 went abandoned on 8 January 2004 and the instant application was not filed until 7 April 2004.

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

It is noted that the relationship between application No. 10/472,856 and the instant application is not recited. Further, although the '856 application is a national stage of a PCT application, PCT/US03/07065 is not listed in the chain of priority between the '856 application and the provisional applications.

Claim Objections

3. Claim 10 is objected to because of the following informalities: With regard to claim 10, it is unclear why Applicant recites "comprising any of" (instead of "comprising"), as several of the elements depend upon details of other elements set forth in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10 - 12, 23, 24, 39 - 41, 45, 54, 55, and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 10 - 12, 23, 24, and 54, use of the term "preferably" renders the scope of the claimed subject matter unclear. With regard to claims 39, 40 and 45, use of the phrase "in particular" renders the scope of the claimed subject matter unclear. It appears that claim 41 should depend from claim 40, instead of claim 39, to provide proper antecedent basis for the claim terms. Claim 55 improperly depends from itself. With regard to claim 72, use of the phrase "which may include" renders the scope of the claimed subject matter unclear.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 95 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Essenpreis et al. Essenpreis et al. teach a measuring arrangement that includes spaced emitter and detector fibers. See Figures 2 and 8 - 10 and the descriptions thereof.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1 - 3, 6 - 10, 18 - 20, 22- 26, 28, 29, 34 - 36, 39, 44, 49, 54, 56, 57, 71 - 74, 76, 78, 79, and 86 - 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin (USPN 6,040,578 - cited by Applicant) in view of Kohl et al. (USPN 5,825,488 - cited by Applicant). Malin et al. teach a method and apparatus for multi-spectral analysis that includes a sampling/illumination and detection portion and base/measurement and processing portion but does not teach that the portions are connected by a communication bundle for providing power to the sampling portion and signals between the portions. Kohl et al. teach an optical measurement system that includes a tissue contacting portion for illuminating and collecting light and an analyzing unit wherein the elements are connected by a cable carrying power to the sampling portion and signals to the analyzing unit. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Malin et al. with the sampling and base portions connected by a cable carrying power and signals, as taught by Kohl et al., since Kohl et al. teach a conventional manner to implement the elements required by Malin et al. Further, it is known to include communications from a glucose sensor to an insulin delivery system to allow automated regulation of insulin injections for diabetic patients. In addition, Kohl et al. teach various arrangements with spacing between the

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emitter and detectors, but do not teach the particular distances set forth in the claim. However, it would have been within the skill level of the art to determine appropriate distances for spacing of the various emission and detection locations to obtain desired measurement results for particular analytes of interest. Further, it would have been within the skill level of the art to provide a plurality of the probes, since it has generally been held to be within the skill level to provide duplicate elements.

10. Claims 4, 5, and 13 - 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Röper et al. (USPN 5,879,373 - cited by Applicant). The combination does not disclose a guide to repeatedly position the sensor portion at the same place on a subject. Röper et al. teaches a sensor head and positioning guide to provide repeatable positioning of an optical measurement device, allowing a user to move more freely between measurement procedures while keeping the sampling position consistent. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include a guide for repeatedly positioning the sensor at a sampling site, as taught by Röper et al., since this allows a user to move more freely while maintaining measurement consistency.

11. Claims 17 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Mills (USPN 5,978,691 - cited by Applicant). The combination does not teach a heater as part of the sensor portion. Mills teaches that a heater in the measurement portion can provide more accurate measurement results. It would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the combination to include a heater, as taught by Mills, since this provides more accurate measurement results.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Suzuki (USPN 5,632,273 - cited by Applicant). The combination does not teach that the sensor probe includes "folding optics". Suzuki teaches a sensor arrangement for a lower profile design using "folding optics". It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include "folding optics", as taught by Suzuki, since this is an alternate arrangement of illumination elements that provides a lower profile sensor design.

13. Claims 21, 58, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Halpern (USPN 5,687,717 - cited by Applicant). The combination does not teach a docking station to receive the base module. Halpern teaches a physiological measurement system that includes base modules and a docking station, wherein the base module can perform some functions, but the docking station includes a more powerful processor to provide more complex or more accurate analysis of the measured data. Further, Halpern teaches that wireless connections can be used for communication between the docking station and base module. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include a docking station, as taught by Halpern, since this allow more complex or more accurate analysis of the measured data.

14. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Sakai et al. (USPN 5,131,391 - cited by Applicant). The combination does not teach an LED for dilation. Sakai et al. teaches a measurement arrangement that includes illumination and heating LEDs to provide increased circulation and improved measurement results. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include an LED for dilation, as taught by Sakai et al., since this provides improved measurement results.

15. Claims 31 - 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Shemwell et al. The combination teaches all of the features of the claimed invention except that quick connect/coupling is used in the communication bundle. Shemwell et al. teach an optical measurement system that includes optical fibers and electrical elements that include a connector between a measurement sensor and a monitor device that allows the patient contacting portion to be a disposable element that can be replaced for use on a different patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the combination with a connector in the communication bundle, as taught by Shemwell et al. since this allows the patient contact portion to be a disposable element.

16. Claims 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al. and Kohl et al. as applied to claim 1 above, and further in view of Thomas et al. Thomas et al. teach an apparatus for tailoring spectroscopic calibration

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models that includes a generic calibration model based upon mean-centered (processed) spectral calibration data and direct analyte measurements. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Malin et al. as modified by Kohl et al. with calibration means that include paired data points of processed spectral measurements and reference biological parameter values, since Thomas et al. teach that this allows the resulting system to be better tailored to the user.

17. Claims 97 - 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenpreis et al. as applied to claim 96 above. Essenpreis et al. teach all of the features of the claimed invention except for the particular distances set forth in the claim. However, it would have been within the skill level of the art to determine appropriate distances for spacing of the various emission and detection locations to obtain desired measurement results for particular analytes of interest.

Allowable Subject Matter

18. The following is a statement of reasons for the indication of allowable subject matter: Applicant cites several references related to non-invasive optical measurement of analyte concentrations. However, the prior art does not teach or suggest an apparatus for non-invasive measurement of glucose concentrations that includes any of the limitations of claims 11, 12, 27, 37, 38, 40 - 43, 45 - 48, 50, 51, 55, 60 - 65, 69, 70, 75, 77, and 80 - 85, in combination with the other claimed limitations.

19. Claims 27, 37, 38, 42, 43, 46 - 48, 50, 51, 60 - 65, 69, 70, 75, 77, and 80 - 85 are objected to as being dependent upon a rejected base claim, but would be allowable if

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rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Claims 11, 12, 40, 41, 45, and 55 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

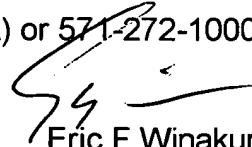
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur
Primary Examiner
Art Unit 3768